

CERTIFICATE OF ELECTRONIC TRANSMISSION 37 C.F.R. § 1.8	
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October 12, 2007	<i>Michael C. Barrett</i>
Date	Michael C. Barrett

PATENT

In the United States Patent and Trademark Office

In re Application of:
Russell Mumper et al.

Serial No.: 10/072,320

Filed: February 7, 2002

For: pH-Sensitive Mucoadhesive Film-Forming
Gels and Wax-Film Composites Suitable for
Topical and Mucosal Delivery of Molecules

Confirmation No.: 5127

Group Art Unit: 1618

Examiner: Hartley, Michael G.

Atty. Dkt. No.: NANO:002USD1

**Paper Correcting Appeal Brief
in Response to Notice of Non-Compliant Appeal Brief Dated September 13, 2007**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This paper responds to the Notice of Non-Compliant Appeal Brief Dated September 13, 2007. The one-month date for response is October 15, 2007 (October 13, 2007, falls on a Saturday). No fee is believed to be due. However, should any fee be required for any reason relating to this document, please consider this paragraph as authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from Fulbright & Jaworski L.L.P. Deposit Account No.: 50-1212/NANO:002USD1/MCB.

Favorable reconsideration of the application is respectfully requested.

Appeal Brief Amendments/Corrections begin on page 2.

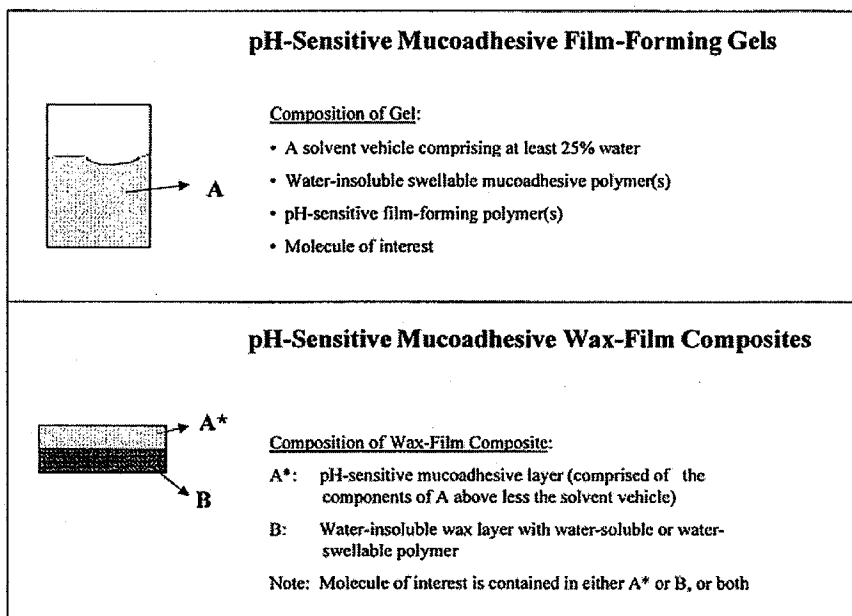
Remarks begin on page 5.

Appeal Brief Amendments/Corrections

Please amend the "Summary of Claimed Subject Matter" beginning on page 3 of the Appeal brief as follows. Only the first paragraph is amended, but Applicants have included the entire "section," for reference, as requested in the Office's Notice of Non-Compliant Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 33 is the only pending independent claim and recites: "A wax-film composite comprised of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer." The invention generally concerns a particular phrase "wax-film composite[[,]]" which is defined as a bi-layer film with bonded layers. See specification, page 18, 2nd full paragraph. The bi-layer composite includes (1) a pH-sensitive mucoadhesive layer bonded to (2) a water-insoluble wax layer. See *id.* The bottom half of Figure 1 illustrates a representative, but non-limiting embodiment as follows:



The pH-sensitive mucoadhesive layer may be present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer may be present at a concentration of 10% to 80% by weight. *See* specification, page 7, 1st paragraph and page 18, 2nd full paragraph. The pH-sensitive mucoadhesive layer may include (1) at least one water-insoluble swellable mucoadhesive polymer, (2) at least one pH-sensitive film-forming polymer, and (3) at least one molecule of interest. *See* specification, page 7, 1st paragraph; *see also* Figure 1. The water-insoluble swellable mucoadhesive polymer may be polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol. *See* specification, page 7, 2nd paragraph. The water-insoluble swellable mucoadhesive polymer may be Noveon or Carbomer. *See id.* The water-insoluble swellable mucoadhesive polymer may be present in the pH-sensitive mucoadhesive layer at a concentration from 0.1% to 20% by weight. *See id.* The pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer may be a copolymer of methacrylic acid and acrylic or methacrylic ester. *See* specification, page 7, 3rd paragraph. The pH-sensitive film-forming polymer may be present in the pH-sensitive mucoadhesive layer at a concentration from 0.05% to 10% by weight. *See* specification, page 7, 5th paragraph. The pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer may be a Eudragit polymer, or chemical derivative thereof. *See* specification, page 7, 3rd paragraph.

The water-insoluble wax layer may include at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C and at least one water-soluble or water-swellable polymer. *See* specification page 7, 4th paragraph and page 18, 1st full paragraph. The wax may be DENTSPLY® Utility Wax, beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax. *See* specification, page 7, 5th paragraph. The water-soluble or swellable polymer may be present in

the insoluble wax layer at a concentration from 0.05% to 10% by weight. *See id.* The water-soluble or water-swellaable polymer may be tragacanth, polyvinyl, pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellaable. *See specification, paragraph spanning pages 7-8.*

The molecule of interest may be contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer. *See Specification, page 8, 1st incomplete paragraph; see also Figure 1.* The molecule of interest may include an active pharmaceutical compound such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistimine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migrane, anti-fungal, a sweetner, a flavoring agent, a diagnostic agent, or a combination thereof. *See specification, page 8, 1st full paragraph. The molecule of interest may be a peptide or protein. See id.*

The wax-film composite may be applied to an application site including: the skin, mouth, vagina, nasal cavity, or other accessible mucosal site. *See specification, page 8, 1st full paragraph. The wax-film composite may adhere to the application site for at least one hour. See id.* The wax-film composite may have a total thickness of less than 5 mm. *See id.*

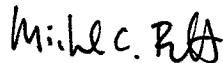
Remarks

The Notice asked that Applicants correct the Appeal Brief's Summary of Claimed Subject Matter section. Applicants respectfully submit that the original section complied with the rules. The original section properly included a "concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters." 37 C.F.R. § 41.37(c)(1)(v).

Nevertheless, in the spirit of cooperation, Applicants have amended the section-at-issue to quote the only independent claim in the appeal—claim 33. The subject matter of that claim is explained concisely in accordance with the rules. The claimed invention is "mapped to the independent claims on appeal," as requested in the Notice.

Applicants appreciate the clarifications offered in the remaining sections of the Notice. Applicants believe this case is in form for action on appeal. Applicants respectfully request favorable consideration of the application. It is believed that the claims are in condition for allowance. If the Examiner has any questions, please contact the undersigned attorney.

Respectfully submitted,



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